Montana Non-infectious Disease Investigation Protocol

Introduction

These guidelines have been provided to ensure a standardized and coordinated response from the Montana Department of Public Health and Human Services (DPHHS) employees who receive calls regarding suspected clusters of cancer, chronic disease, birth outcomes, or environmentally-related diseases.

The investigation can be divided into four stages: coordination, verification, investigation, and epidemiological study. The first three stages are described here. Conducting an epidemiological study is beyond the scope of this document. The boundaries between these stages are flexible, and the steps do not necessarily follow the order indicated.

In each stage decisions must be made. The results of these decisions must be communicated to those reporting the cluster, local health jurisdictions, and to the public.

The investigation process can be described by the following steps:

Stage I: Coordination

- Receive report, pass to proper DPHHS team member
- Contact local health jurisdictions
- Work out response plan

Stage II: Verification

- Verify cases
- Compare rates
- Decide if report meets investigation criteria

Stage III: Investigation

- Collect risk factor information on cases
- Decide if cases can be explained by recognized risk factors
- Obtain information on local exposures of interest
- Decide if cluster meets study criteria

During and after each stage:

- Communicate findings
- Document findings

Stage 1 – Coordination

Step 1: Record the initial report

Suspected clusters may be reported to any department. Anyone who receives a call, letter or e-mail must respond with speed and sensitivity. The way in which the initial report is handled will greatly affect perceptions of DPHHS. A positive initial response can help to diffuse concerns a caller may have.

When a cluster is reported, the Cluster Report Form (Appendix A) should be completed. This form organizes key points about the reported cluster and provides prompts for further information. The caller's real concern may only emerge in response to careful questioning. Getting as much information as possible about the caller and index cases during the initial call can save time and resources later. It also assures the caller that the report is being treated seriously. During the call you should identify yourself, tell the caller what actions will be taken, and state when the caller can expect a response.

If the disease of concern falls out of your knowledge base, get the name and number of the caller and fill in as much of the Request Form as possible. Forward the call or pass the information to the appropriate person for follow-up. Do not simply refer the caller to another department since the caller may become discouraged and not call again. People who will handle cluster investigations by disease category are listed in Appendix C.

In many cases, you may be able to provide information that can immediately satisfy the caller. Often people only need help understanding and interpreting their observations about adverse health effects.

After the call has been made, log the call in the non-infectious disease calls database.

Step 2: Contact local health jurisdictions

After the initial information has been gathered, it must be decided who will conduct the follow-up. Since the concern is in their locality, local health departments must be contacted immediately.

Step 3: Work out a response plan

Once all of the players have been informed, a response plan can be worked out. If the local health department prefers that DPHHS conducts the investigation, then progress to Stage 2. Otherwise DPHHS will provide assistance and educational materials to the local health department as requested.

In either case the decision should be logged in the non-infectious disease calls database.

Stage 2 – Verification

Step 1: Form an initial case definition

The initial case definition asks the questions “what,” “who,” “where,” and “when.”

- What is the specific disease, symptom, or health event of concern?
- Who are the index cases (first reported cases)?
- Where is the affected geographical area or population group?
- What are the specific exposures of concern?
- When did this specific disease, symptom or health event occur?

Step 2: Decide if the report merits a preliminary investigation

A preliminary investigation is carried out if three criteria are met:

1) Three or more cases found in a defined population (at least two cases for extremely rare diseases)
2) Cases' health effects are related, either through physiology or exposure pathway
3) Cases lived in the associated area during the disease exposure window and not just at the time of diagnosis (e.g. three cases of prostate cancer among nursing home residents would not be considered a cluster)

Step 3: Verify cases

Reported cases should be verified by the appropriate surveillance system. At a minimum the disease diagnosis, time (year) of diagnosis, and location of residence should be verified. The most commonly used surveillance systems used are listed in Appendix C.

Step 4: Find additional cases

Additional people meeting the case definition should be sought out from the appropriate surveillance systems.

Step 5: Compare rates

Compare the rate of disease in the locality (usually county or zip code) to Montana’s overall rate of disease.

The reference population should include all persons at risk. Defining the reference population too narrowly can result in the false identification of a cluster. However,

diseases occur at different rates for different sexes, age groups, and ethnicities, so the demographics of the reference population should be understood.

Step 6: Verify cases with outside sources (if necessary)

In some instances, further validation of cases will be necessary, such as when an index patient has not yet been reported to the appropriate surveillance system. In these instances information about the patient should be solicited from the initial informant and health care providers familiar with the patient, if possible.

Step 7: Decide if the report meets further investigation criteria

Further investigation is merited if one of the following criteria is met:

- There is excess disease. The rates in the locality of interest are greater than the population rates
- The disease is extremely rare or found in an unusual population
- There is intense community concern.

The decision to conduct further investigation will be decided by the investigation advisory group.

All steps: Follow up

Findings must be reported and documented.

E-mail a short synopsis of the findings to:

- DPHHS staff
- Local health department concerned
- DEQ if a specific environmental concern was involved

Personal health information is confidential. To protect patient privacy, all e-mail communication should omit personal identifiers.

Contact the caller by phone with the results and answer any further questions the caller may have. Then mail a follow-up letter with disease-appropriate literature. The local health officer should review the letter as appropriate before sending.

Document findings in the non-infectious disease calls database.

Stage 3 –Investigation

Many clusters are reported because a specific environmental hazard is suspected to be contributing to disease. However, most diseases have several possible risk factors. Risk factors such as smoking and poor diet are found in a large percentage of the community, and the environment may not be causing much, if any, additional risk.

Step 1: Locate recognized risk factors for disease from literature.

Information on known risk factors for the disease should be gathered from the corresponding surveillance program and literature review.

Step 2: Collect information on recognized risk factors from cases.

Information on as many identified risk factors as possible should be obtained from case patients. This information can be obtained from the appropriate surveillance system, the cases themselves, health care providers, and/or next of kin.

Step 3: Decide if cluster is explained by recognized risk factors.

The investigation should continue if known risk factors do not account for the current cluster.

Step 4: Obtain local information on hazard of interest.

If an environmental hazard is suspected, a literature review should be conducted and existing local data on the hazard found. Local data may be available from the Department of Environmental Quality (DEQ), Environmental Protection Agency (EPA), U.S. Geological Survey (USGS), Montana Digital Library (NRIS), or other departments. Environmental samples should not be collected at this point. The purpose of the literature review is to assess biologic plausibility between the reported hazard and disease.

Step 5: Decide if cluster meets study criteria.

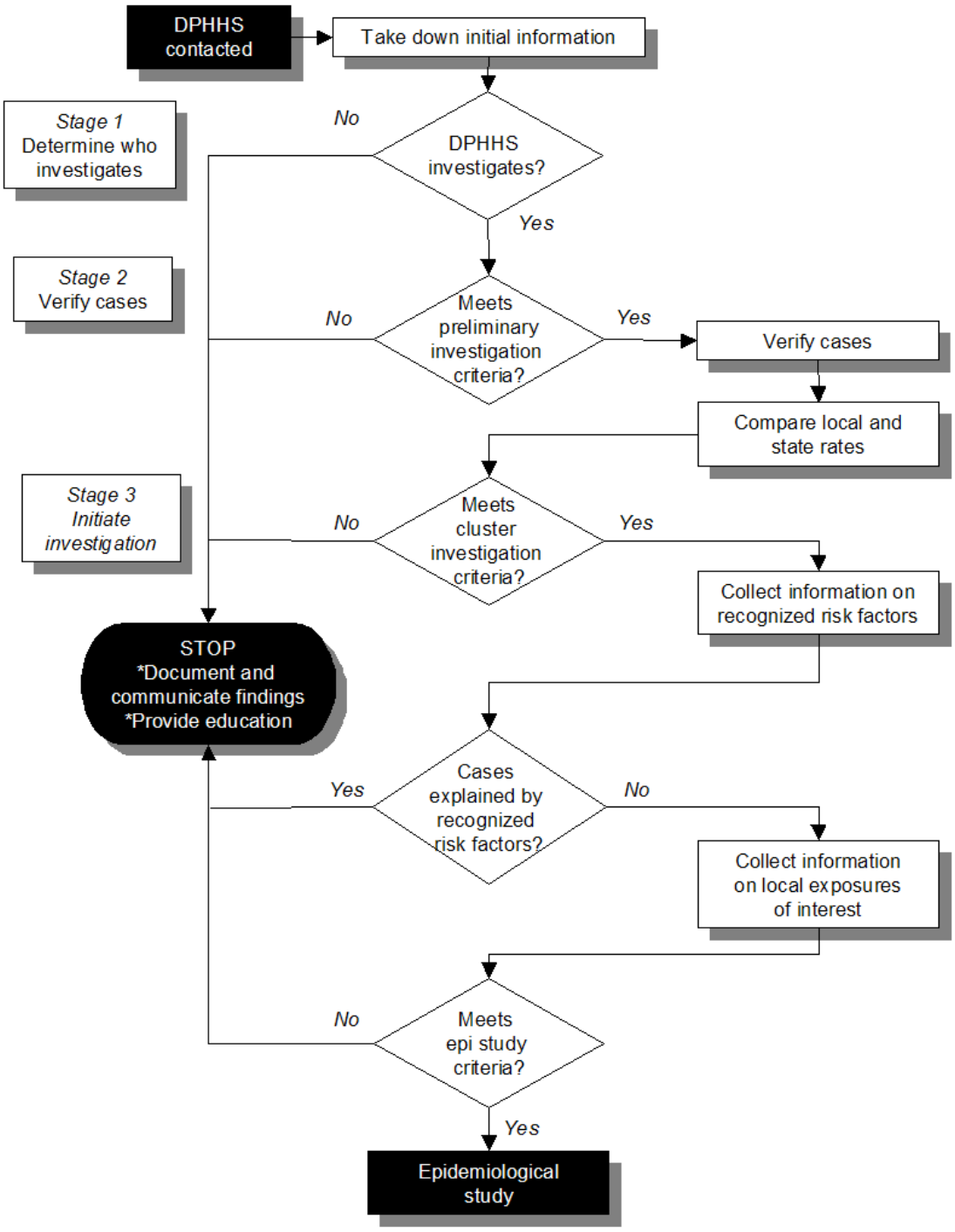
Further investigation is merited if one of the following criteria is met:

- hazard has a biologically plausible contribution to disease of interest
- a sudden increase in rate for this disease was found
- the disease has unknown etiology and unusual exposures exist in this cluster
- there is intense community concern

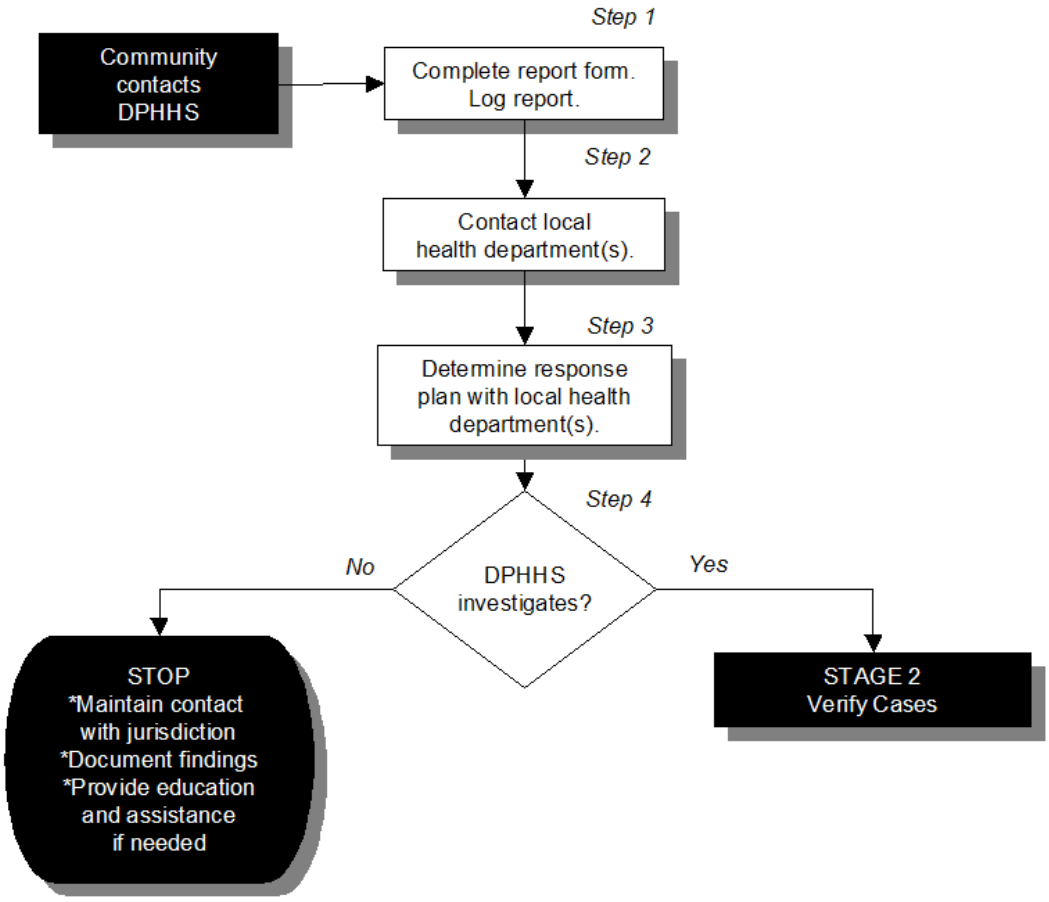
Stage 4 – Epidemiological Study

Further investigation may involve a case-control, cohort, or cross-sectional study. Consultation with appropriate specialists and agencies is recommended. These agencies involved may include the Centers for Disease Control and Prevention (CDC), the Agency for Toxic Substances and Disease Registry (ATSDR), and/or the Environmental Protection Agency (EPA).

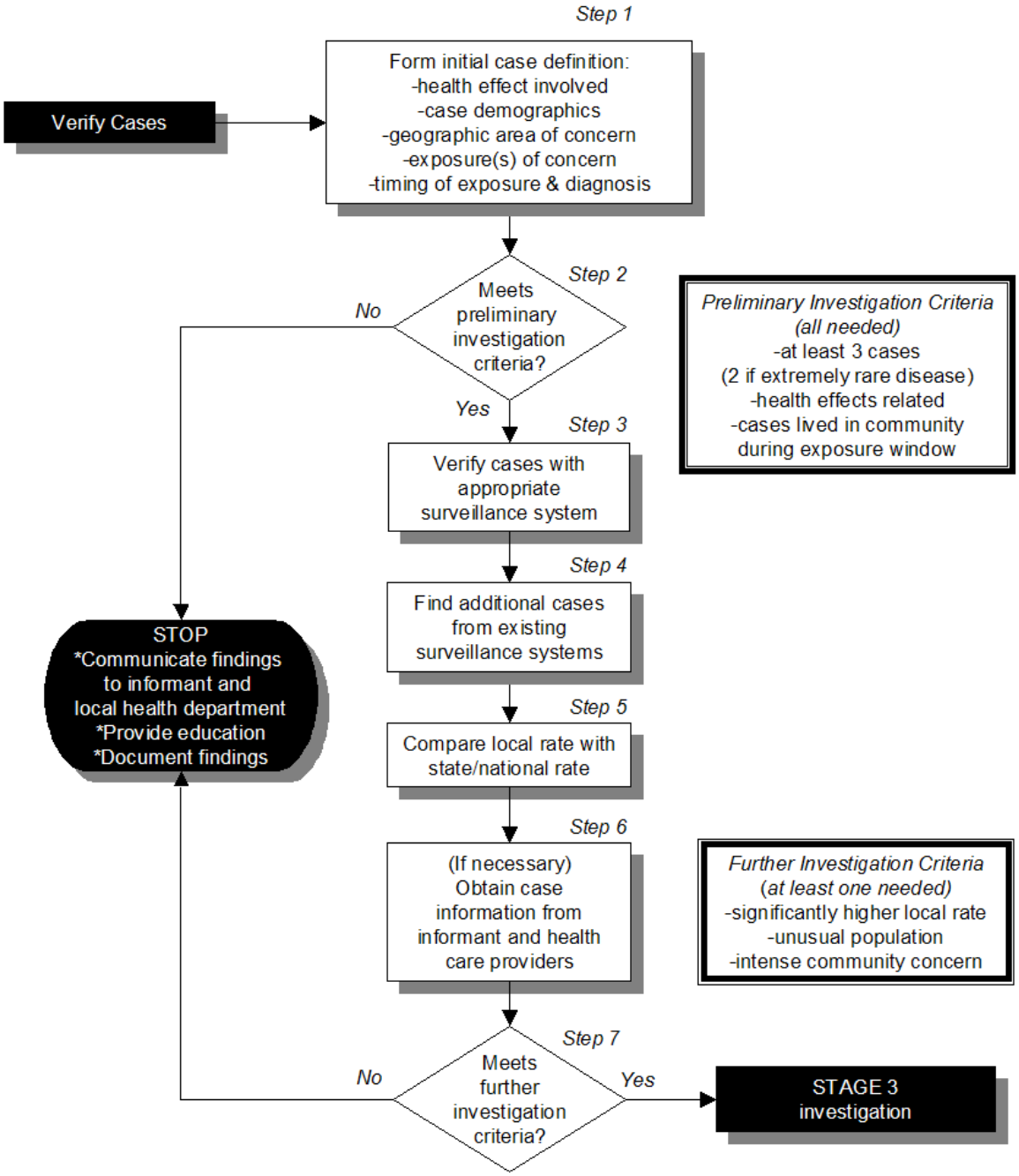
Overview:
Investigation Process



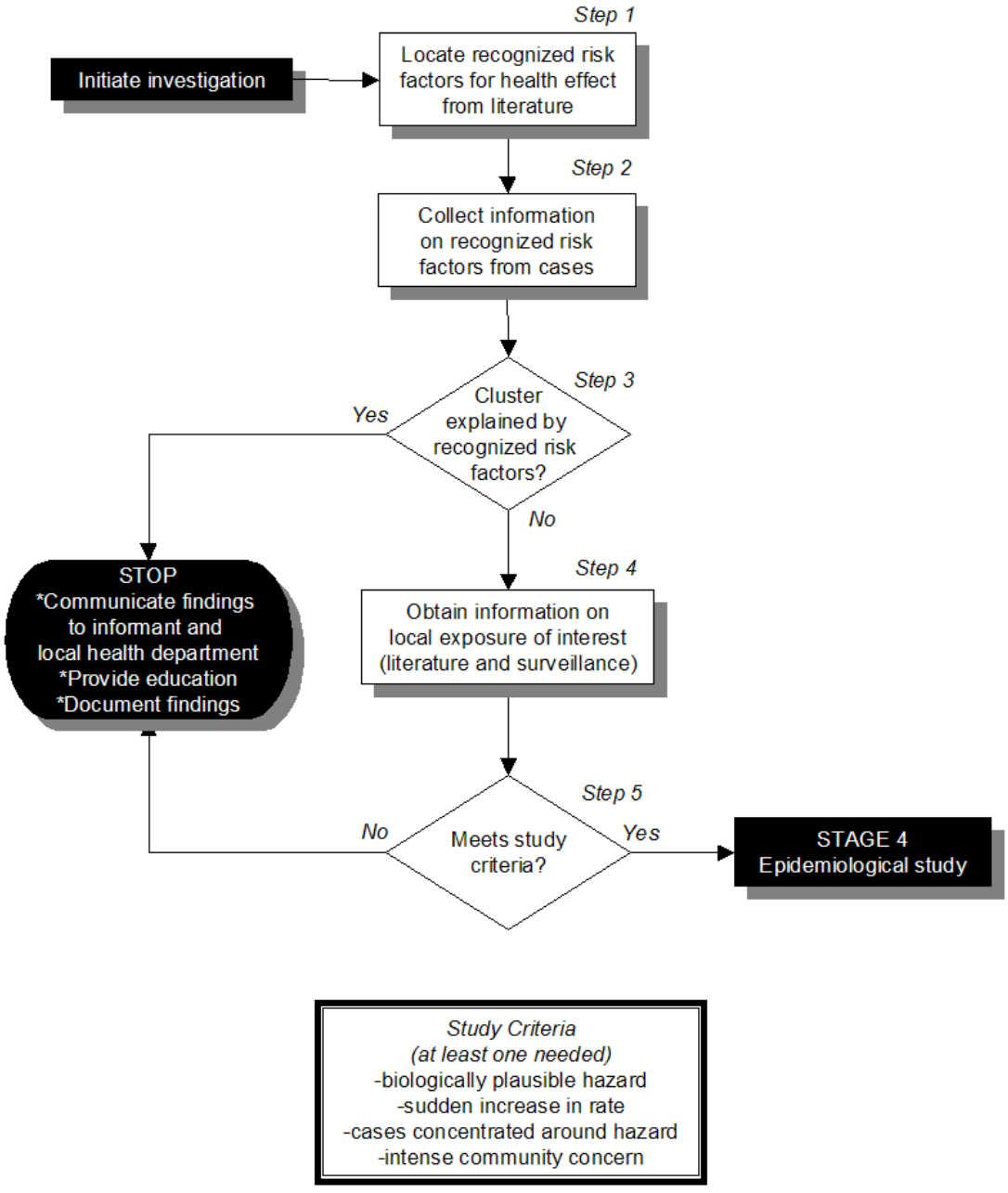
Stage 1: Coordination



Stage 2: Verification



Stage 3: Investigation



Appendix A: Cluster Report Form

Cluster ID#_____

Person completing form……..……Date……

Caller's Name:_____

Address:_____

Telephone number: (home)_____(work)_____

Best time to reach:_____

E-mail:_____

Affiliation:_____

Disease of concern:_____

Other agencies contacted by caller:_____

_____

Additional information:

Appendix B: Cluster Report Form—Case Information

Cluster ID#_____
Case #_____

Case's Name: _____

Telephone number: _____ Sex: male female

Date of Birth:_____ or Age (apx) _____

Address: _____

Dates of Residence: from_____to _____

Ethnicity: White Native American African American Asian Hispanic Other

Diagnosis:_____ Date of diagnosis:_____

Place of diagnosis:_____Who made the diagnosis:_____

Address at diagnosis:_____

Smoker: current former never smoked

Usual job: _____Years worked_____

Year of death *(if applicable)*:_____ Place of death:_____

Additional information:

Steps:	Completed	Expected Completion Date
Updated cluster database	□	_____
Contacted local HD	□	_____
Queried disease database	□	_____
Report to informant	□	_____
Report to HD	□	_____

Appendix C: DPHHS Contacts for Cluster Reports

Type of Call

Birth Defects		
Birth Defects Registry and Newborn Screening Program Manager		
Sib Clack	1216	sclack@mt.gov
Cancer		
Cancer Epidemiologist		
Carol Ballew	6988	cballew@mt.gov
Cardiovascular Disease/ Diabetes		
Epidemiologist		
Carrie Oser	4002	coser@mt.gov
Environmental Concerns		
Environmental Epidemiologist		
Christine Korhonen	1701	ckorhonen@mt.gov

Other Important People

State Medical Officer		
Steve Helgerson	1286	shelgerson@mt.gov
State Epidemiologist		
Todd Damrow	3986	tdamrow@mt.gov

Appendix D: Cluster Reports Disease Specialist Guide

When a call comes in reporting a group of diseases in your specialty:

1. Return the informant's call or send acknowledgement letter or e-mail.

a. Fill out the Cluster Report Form (Apx A) and Case Information Forms (Apx B) as completely as possible. Fill out one Case form for each case known to the informant. These forms can be filled directly into the Non-infectious Cluster Calls Database on the share drive H:\HPS\ALL\Clusters\Non-infectious cluster calls.mdb

b. Acknowledge that their report has been received and an investigation will be conducted. Provide education on the usual frequency, rates and common risk factors for the disease of concern. A sample acknowledgement letter is in Apx E.

c. Let the informant know what steps will be followed and the time frame when s/he can expect to hear results from you.

d. If not already completed, transfer information collected into the Non-infectious Cluster Calls Database on the share drive.

2. Contact the appropriate local health department.

a. Work out a response plan.

b. If the local health department decides to take the lead, provide data and educational materials as needed.

c. If the local health department prefers you to take the lead, follow the Montana Non-infectious Disease Investigation Protocol.

3. Communicate findings.

a. Send initial letter or e-mail to informant with preliminary results.

b. Send completed report to informant, local health department and environmental contacts, if required.

c. Update Non-infectious Cluster Calls Database.

Appendix E: Sample Acknowledgment Letter

<letterhead>

<date>

<informant>
<informant's address>

Dear <informant>,

Thank you for contacting the Montana Department of Public Health and Human Services. I have received your request for information on the number of people with <disease> in <counties> and have begun an investigation.

Unfortunately, no one can say with certainty what caused any one person's <disease>. We can only talk in general terms about the known and suspected factors that increase a person's risk of disease. More information on <disease> and its risk factors can be found on the attached fact sheet.

I hope this information is helpful. I should be able to get the results of our investigation to you by <one month from date>. If you have additional questions about the investigation process, please feel free to contact me.

Sincerely,

<disease specialist>
<address>
<phone number>
<e-mail>

cc: Local Health Department
Division Head, DPHHS Public Health and Safety Division

Appendix F: Sample Cancer Results Letter

<letterhead>

<date>

<informant>
<informant's address>

Dear <informant>,

Thank you for asking about cancer in Montana. You are not alone with questions about cancer and chronic disease. We receive many inquiries from people wondering if the diseases they see occur more frequently in their community than elsewhere.

The Montana Department of Public Health and Human Services (DPHHS) has collected information on Montanans with cancer since 1979. Information on cancer in <counties> is listed in the table below. In order to determine if there are more cancers in these counties compared to the rest of Montana and the entire United States, rates of cancer have been provided. The rates show the number of cancers expected if there were 100,000 people in these counties. Since people with cancer tend to be older, these rates have also been adjusted to take into account the age distributions of the counties.

Cancer, 1979 – 2002

	Number of Cases	Rate per 100,000 people
County 1		
County 2		
Montana	-	
United States	-	

Comparing the rates of cancer in these counties to the state of Montana and the rest of the U.S., there does not appear to be any excess cancer in these counties.

I hope this information is helpful to you. Please feel free to contact me with any further questions.

Sincerely,

<disease specialist>
<address>
<phone number>
<e-mail>

cc: Local Health Department 1
Local Health Department 2
Division Head, DPHHS Public Health and Safety Division

Appendix G: Sample Non-cancer Results Letter

<letterhead>

<date>

<informant>
<informant's address>

Dear <informant>,

Thank you for asking about <disease> in Montana. You are not alone with questions about cancer and chronic disease. We receive many inquiries from people wondering if the diseases they see occur more frequently in their community than elsewhere.

The Montana Department of Public Health and Human Services (DPHHS) does not collect information on <disease>. Nationally, <what is known>. Information about <disease> in Montana comes from <source>.

Unfortunately, no one can say with certainty what caused any one person's <disease>. We can only talk in general terms about the known and suspected factors that increase a person's risk of disease. More information on <disease> and its risk factors can be found on the attached fact sheet.

I hope this information is helpful to you. Please feel free to contact me with any further questions.

Sincerely,

<disease specialist>
<address>
<phone number>
<e-mail>

cc: Local Health Department
Division Head, DPHHS Public Health and Safety Division